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Everolimus- Versus Novolimus-Eluting Bioresorbable Scaffolds for the Treatment of Coronary Artery Disease

A Matched Comparison

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ABSTRACT

OBJECTIVES The purpose of this study was to compare the 1-year outcome of everolimus-eluting bioresorbable scaffolds (eBRS) and Novolimus-eluting bioresorbable scaffolds (nBRS) in patients undergoing percutaneous coronary intervention in a real-life clinical practice scenario.

BACKGROUND eBRS and nBRS are available and have been proved safe for coronary artery stenting in well-selected patients.

METHODS Consecutive patients who underwent bioresorbable scaffold implantation were evaluated retrospectively via 2:1 propensity matching. Target lesion failure comprising cardiac death, target vessel myocardial infarction, and target lesion revascularization was examined after 12 months, along with its individual components as well as scaffold thrombosis.

RESULTS A total 506 patients were available for matching. Of these, 212 eBRS patients (mean age = 62.9 years) and 106 nBRS patients (mean age = 63.1 years) were analyzed after matching. Baseline characteristics and clinical presentation were comparable in both groups. Acute coronary syndromes were present in 53.3% of the eBRS group and in 48.1% of the nBRS group ($p = 0.383$). Lesion characteristics were also similar. Pre-dilation (99.5% vs. 98.1%; $p = 0.218$) and post-dilation (84.4% vs. 86.8%; $p = 0.576$) were performed in the same proportion of matched eBRS and nBRS patients, respectively. The 1-year rates of target lesion failure (4.7% vs. 4.5%; $p = 0.851$), target lesion revascularization (2.6% vs. 3.5%; $p = 0.768$), cardiac death (1.5% vs. 2.0%; $p = 0.752$), and definite scaffold thrombosis (2.0% vs. 1.0%; $p = 0.529$) did not differ significantly between the eBRS and nBRS groups.

CONCLUSIONS The present study reveals comparable clinical results for the 2 types of bioresorbable scaffolds when used during routine practice, but further evidence from randomized controlled trials is needed. (J Am Coll Cardiol Intv 2017;10:477–85) © 2017 by the American College of Cardiology Foundation.

Bioresorbable scaffolds (BRS) have entered routine clinical practice with good reason, as they have demonstrated similar clinical outcomes compared with drug-eluting metal stents (DES) and noninferiority regarding antirestenotic efficiency (1-4). In addition, several positive effects related to their dissolving character have been observed, including late luminal enlargement and the restoration of vessel vasomotion (5,6). Several different materials and types of BRS are currently

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ABBREVIATIONS AND ACRONYMS

BRS = bioresorbable scaffold(s)

DAPT = dual-antiplatelet therapy

DES = drug-eluting metal stent(s)

eBRS = everolimus-eluting bioresorbable scaffold(s)

MACE = major adverse cardiac event(s)

nBRS = Novolimus-eluting bioresorbable scaffold(s)

PLLA = poly-L-lactic acid

TLF = target lesion failure

TLR = target lesion revascularization

under investigation, with poly-L-lactic acid (PLLA) providing the most common basis. At present, 2 PLLA-based BRS are commercially available in Europe: an everolimus-eluting BRS (eBRS) (Absorb Bioresorbable Vascular Scaffold, Abbott Vascular, Santa Clara, California) and a Novolimus-eluting BRS (nBRS) (DESolve scaffold, Elixir Medical, Sunnyvale, California) (7). Both are degraded via hydrolysis and the Krebs cycle into carbon dioxide and water. The 2 BRS share several mechanical characteristics, including a strut thickness of approximately 150 μm. In addition to the eluted drug, however, there are slight differences in design and mechanical properties that could potentially have an impact on procedural and clinical outcomes.

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The most widely investigated BRS is the eBRS, and several studies that were carried out mostly with selected patients have been reported. A recent meta-analysis demonstrated that target lesion revascularization (TLR) occurs in 2.7% of patients after 1 year, which is comparable with the incidence with DES (8). nBRS were evaluated in a prospective, single-arm study that showed a TLR rate of 3.3% after 1 year (9). A direct comparison of the 2 BRS types is presently not available, however, and there is also a lack of data on the use of these devices in everyday clinical practice. Therefore, the aim of the present analysis was to make a direct comparison of the procedural performance and clinical results of eBRS and nBRS during routine clinical practice.

METHODS

STUDY POPULATION. All consecutive patients treated with either the eBRS or nBRS at the University Hospital of Giessen, Germany, between October 2012 and December 2015 were evaluated. The nBRS has been available for implantation since March 2014. Patients were included in a local registry, the German-Austrian ABSORB Registry or the DESolve post-market registry. All of these studies were approved by the ethics board of Justus Liebig University of Giessen, Germany. General criteria for BRS implantation were any evidence of myocardial ischemia, including electrocardiographic findings, cardiac enzymes, and symptoms; reference vessel diameter between 2.3 and 4.0 mm; age ≥18 years; and the absence of contraindications to dual-antiplatelet therapy (DAPT) or scaffold components. Because of evidence of a learning curve, which has been previously described, the first 100 patients treated with the eBRS were excluded from this investigation (10). A learning curve was not observed for the patients treated with the nBRS (Online Table 1). Furthermore, only patients undergoing single-vessel intervention during the index procedure were considered for propensity matching. The study flowchart is displayed in **Figure 1**.

eBRS. The eBRS consists of a backbone with zigzag hoops and bridges and is composed of PLLA. It has an elution containing poly-D-L-lactic acid and 100 μg/cm^2 anti-inflammatory everolimus in a 1:1 ratio. The struts are approximately 150 μm thick, leading to a crossing profile of 1.4 mm. Radiopaque markers are located at both ends. Full dissolution is achieved within 2 to 3 years (11). Three different diameters (2.5, 3.0, and 3.5 mm) and 5 different lengths (8, 12, 18, 23, and 28 mm) are available.

nBRS. The nBRS scaffold has a PLLA backbone of tubular hoops connected by bridges, and its elution is the anti-inflammatory drug Novolimus at 5 μg/mm scaffold length. Strut thickness is approximately 150 μm, and the crossing profile is 1.4 mm. Both ends have radiopaque markers for visualization. The degradation process takes approximately 1 to 2 years. Presently, 4 different diameters (2.5, 3.0, 3.25, and 3.5 mm) and 3 different lengths (14, 18, and 28 mm) are available. The nBRS has 2 unique features: overexpansion up to 0.5 mm above nominal is possible without an inherent risk for strut fracture, leading to a wider safety margin. The nBRS is also able to self-correct for minor malapposition, because it can expand to the nominal diameter in cases of underdeployment.

STUDY PROCEDURE. Implantation of BRS was performed primarily via radial access, if feasible. Periprocedural unfractionated heparin (5,000 IU) and 500 mg aspirin were administered. Pre-dilation was mandatory and post-dilation was highly recommended, but the decision to use the latter was ultimately left to the implanting physician's discretion.

The type of post-procedural DAPT was prescribed according to the patient's clinical presentation and current guidelines (12). Because of limited evidence regarding DAPT duration and BRS, DAPT was prescribed for 12 months in all patients.

BASELINE EXAMINATION AND FOLLOW-UP. Baseline testing included documentation of medical history and medications, physical examination, 12-lead electrocardiography, and laboratory testing. Patients were followed-up via telephone and standardized questionnaires or office visits.